

REQUEST FOR PROFESSIONAL SERVICES

TASK OFFICER: Edward Hudgens, Chemist, EB/EPHD/NHEERL, tel: 919-966-0642, fax: 919-966-0655

SUGGESTED CONTRACTOR:

San Francisco State University, Office of Research & Sponsored Programs
1600 Holloway Avenue, ADM 471
San Francisco, CA 94132
Contact: Alison Sanders
Tel: (415) 338-7094
Fax: (415) 338-2493
Email: asanders@sfsu.edu

SFSU's DUNS #: 942514985

Representing: Rosemarie Bowler, Ph.D.

PERIOD OF PERFORMANCE: 36 months from date of issuance, a suggested period of October 1, 2012 – September 30, 2015. This Period of Performance for this severable service should consist of one 12 month Base Year and two 12 month optional quantities. Interim payments are allowed based on the following schedule, for the Base Year:

1. After EPA receives notification that the individualized study results have been mailed, receipt of the approved public meeting presentation, and proof that meeting has occurred, 15%
2. After EPA acceptance of the Manganese in Hair Sample Analysis Report, 15%
3. After EPA acceptance of Draft Manuscript 1, 30%
4. After EPA acceptance of Draft Manuscript 2, 30%
5. After EPA acceptance of the Final Report for the Base Year, 10%

For Option Year One:

1. After Manuscript 1 has been through the EPA Clearance Process and submitted to the specified Journal. 15%
2. After Manuscript 1 has been accepted by the Journal, 10%
3. After Manuscript 2 has been through the EPA Clearance Process and submitted to the specified Journal. 15%
4. After Manuscript 2 has been accepted by the Journal, 10%
5. After EPA acceptance of Draft Manuscript 3, 30%
6. After EPA acceptance of outline of Draft Manuscript 4, 10%
7. After EPA acceptance of the Final Report for Option Year One, 10%

For Option Year Two:

1. After Manuscript 3 has been through the EPA Clearance Process and submitted to the specified Journal. 15%
2. After Manuscript 3 has been accepted by the Journal, 10%
3. After EPA acceptance of Draft Manuscript 4, 20%

4. After Manuscript 4 has been through the EPA Clearance Process and submitted to the specified Journal. 15%
5. After Manuscript 4 has been accepted by the Journal, 10%
6. After EPA acceptance of Draft Materials for an EPA Report, 20%
7. After EPA acceptance of the Final Report for Option Year Two, 10%

SOLE SOURCE JUSTIFICATION:

The procurement of the services specified in the attached Request for Professional Services is recommended to be processed without full and open competition. The project "An Epidemiologic Health Study of Manganese Exposure in East Liverpool, Ohio" was selected by Region 5 to be funded under the Regional Applied Research Effort sponsored by the Office of Science Policy. The proposed contractor, Rosemarie Bowler of San Francisco State University, conducted an epidemiologic health study of manganese exposure in East Liverpool, Ohio in November 2011. She conducted similar studies in Marietta, Ohio and Mt. Vernon, Ohio as part of a previous RARE project. The data from the East Liverpool study must be analyzed and reported using the same statistical techniques previously employed for the other two studies so that the study results are equivalent and comparisons can be made across the three communities. In order to do this community based study, Dr. Bowler gained the trust of the community and enrolled individual participants. Therefore, it is imperative that she lead any effort to report the results of this study. Due to proposed contractor's unique capabilities, it is recommended that this professional services contract be granted without competition.

AUTHORITY AND FAR REFERENCE

The basis for this recommendation is 41 U.S.C. 253(c)(1); FAR 6.302-1; only one responsible source.

STATEMENT OF WORK

A. Background Information

Potential neurotoxicity from airborne Manganese (Mn) exposure has been a community and risk assessment concern for more than a decade in Region 5 (e.g. OH, MI). The RARE program funded a 2009-2010 Mn health study in Marietta OH near a large industrial emitter of airborne Mn, led by Rosemarie Bowler of San Francisco State University. Mt. Vernon OH, demographically similar to Marietta but without large industrial Mn emission sources, was used as the comparison community for Marietta. Initial Marietta-Mt. Vernon comparisons generally indicate a lack of major health effect differences between the two towns. In November 2011, Dr. Bowler conducted a study using the same protocols, staff and measurement techniques in East Liverpool OH. Some of the highest chronic US residential Mn inhalation exposures are likely to have occurred in this area, with outdoor Mn concentrations up to 50-fold higher than the previous two Ohio towns.

The proposed comparisons of the results from the enrolled cohorts in these three communities are important in that either positive results (differences between East Liverpool and comparison communities) or negative results (little or no differences among communities) inform the issue of potential health effects of residential airborne Mn exposure, a recognized gap in Mn health effects literature. Therefore, either outcome can help inform the need for greater airborne Mn control. In addition, the present proposal addresses the USEPA Administrator's environmental justice priority. The poverty rate is higher in East Liverpool (25.2%) than in Marietta (16.9%), Mt. Vernon (15.6%), the State of Ohio (7.8%) or the U.S. (9.2%).

B. Purpose and Objectives

To evaluate whether long term (minimum 10 years) residential airborne Mn exposure can affect human health, the Contractor shall compare already available study data from adult residents of Marietta and Mt. Vernon with the results with those of East Liverpool for biomarkers (blood metals, toenails, hair), medical tests (symptoms; illnesses; Unified Parkinson's Disease Rating Scale evaluation), functional tests (mood; neuropsychological tests such as working memory and attention, verbal skills, motor dexterity/strength, visual tracking speed); and questionnaires (life style habits; work; dietary Mn). Key research questions include:

- Are blood and plasma Mn (controlled for Cd, Hg, and Pb exposure by measuring these metals in whole blood; controlled for Fe status and liver function by measuring plasma ferritin and the hepatic enzymes ALT and GGT, respectively) significantly elevated in East Liverpool adult residents vs. those in Marietta and Mt. Vernon? An additional novel diagnostic biomarker using toenails and hair shall be used to assess longer term Mn exposure (7-10 months).
- What differences in environmental and lifestyle factors may contribute to blood, hair, and toenail Mn levels in East Liverpool residents?
- Is Mn body burden associated with altered neurological and neuropsychological function, or medical symptoms and illnesses?
- Do health outcomes (e.g. neuropsychological test results) differ among the three towns?
- Can Mn exposure-effect relationships with health and illness be shown through use of a

cumulative exposure index?

The November 2011 community based study was a high visibility research initiative within this Region. Several newspaper articles and television reports featuring Rosemarie Bowler of San Francisco State University tracked the progress of the study during the field data collection portion of this project. The Region has since received enquiries from the media asking for updates and any findings. In order to address community concerns, the Contractor shall prepare and present the results of this study in a public meeting in East Liverpool, Ohio. The proposed time frame for this meeting is October – November 2012 (approximately 12 months after data collection).

C. Specific Objectives/Milestones to be Performed by the Contractor

The Contractor shall send individualized reports to the East Liverpool, Ohio study participants; prepare and conduct a public meeting in East Liverpool to present and explain results of the study; measure the Mn content of hair samples and report the results to the EPA; analyze data; produce reports and manuscripts for this study.

The Contractor shall submit a Work Plan of no more than 3 pages for each 12 month period. This Work plan shall describe the proposed level of effort and deliverables schedule. The Contractor shall abide by the requirements of the previously EPA approved Quality Assurance Project Plan (QAPP) for this study. Their Work Plan will serve as an update to the QAPP.

In the Base Year, the Contractor shall perform the following Tasks:

1. Send individualized reports to the East Liverpool, Ohio study participants. The Contractor shall include their contact information as part of these reports and be prepared to answer questions from study participants. The Contractor shall prepare and conduct a public meeting in East Liverpool to present and explain results of the study, to date. The Contractor shall be responsible for finding and renting the meeting location. The Contractor, in conjunction with representatives from the State of Ohio, shall publicize the date, location and topic material for the public meeting. The Contractor's presentation materials will require EPA review and approval prior to the public meeting. The Contractor shall deliver a copy of their presentation materials and script to the EPA at least three weeks prior to the public meeting. The EPA will review the presentation and obtain clearance and management approval. The Contractor shall coordinate their actions and the timing of the public meeting with representatives of Region 5 (George Bollweg) and State of Ohio (Greg Stein).
2. Measure the Mn content of hair samples and report the results to the EPA. As part of Contract EP-11-D-000424, the Contractor analyzed toenail samples collected during the November 2011 study in East Liverpool for Mn content. The Contractor shall use the same or an equivalent method to analyze all of the hair samples collected during this study. The Contractor shall ensure that any changes in the sample preparation, analysis, or data handling procedures do not affect the ability to make comparisons between the toenail and hair datasets.

3. Prepare a journal article suitable for submission to a peer-reviewed journal which specializes in topic areas such as environmental health, epidemiology, clinical results, or exposure assessment (hereafter referred to as Manuscript 1). The Contractor shall prepare an outline of the article with suggested conclusions and the anticipated journal for submission for comment by the EPA. The EPA will provide comments on the outline and approval for the target journal within 21 days of receipt. The Contractor shall write a rough draft of the article based on the reviewed outline suitable for EPA and any other coauthor's review. The EPA will provide comments on the draft within 21 days of receipt.
4. Prepare a journal article suitable for submission to a peer-reviewed journal which specializes in topic areas such as environmental health, epidemiology, clinical results, or exposure assessment (hereafter referred to as Manuscript 2). The Contractor shall prepare an outline of the article with suggested conclusions and the anticipated journal for submission for comment by the EPA. The EPA will provide comments on the outline and approval for the target journal within 21 days of receipt. The Contractor shall write a rough draft of the article based on the reviewed outline suitable for EPA and any other coauthor's review. The EPA will provide comments on the draft within 21 days of receipt.
5. Prepare a Final Report of no more than 3 pages which details the data analysis results to date. The Contractor shall include all biological sample laboratory analysis results as an addendum to this Report. A draft of this report shall be due 10 months after the award of this Contract. The EPA will review and provide comment on this report within 21 days. The contractor shall incorporate any EPA comments and provide a final version of this report no more than 30 days after the receipt of the EPA's comments.

In Option Year One, the Contractor shall perform the following Tasks:

1. Incorporate any EPA comments to the draft of Manuscript 1, clear the article through the EPA Clearance Process and submit the article to the specified Journal.
2. Incorporate journal reviewer comments and submit the final Manuscript 1 article to the journal for publication. The Contractor shall be responsible for all publication charges. The Contractor shall submit the final journal acceptance notice upon receipt.
3. Incorporate any EPA comments to the draft of Manuscript 2, clear the article through the EPA Clearance Process and submit the article to the specified Journal.
4. Incorporate journal reviewer comments and submit the final Manuscript 2 article to the journal for publication. The Contractor shall be responsible for all publication charges. The Contractor shall submit the final journal acceptance notice upon receipt.

5. Prepare a journal article suitable for submission to a peer-reviewed journal which specializes in topic areas such as environmental health, epidemiology, clinical results, or exposure assessment (hereafter referred to as Manuscript 3). The Contractor shall prepare an outline of the article with suggested conclusions and the anticipated journal for submission for comment by the EPA. The EPA will provide comments on the outline and approval for the target journal within 21 days of receipt. The Contractor shall write a rough draft of the article based on the reviewed outline suitable for EPA and any other coauthor's review. The EPA will provide comments on the draft within 21 days of receipt.
6. Prepare a journal article suitable for submission to a peer-reviewed journal which specializes in topic areas such as environmental health, epidemiology, clinical results, or exposure assessment (hereafter referred to as Manuscript 4). The Contractor shall prepare an outline of the article with suggested conclusions and the anticipated journal for submission for comment by the EPA. The EPA will provide comments on the outline and approval for the target journal within 21 days of receipt.
7. Prepare a Final Report of no more than 4 pages which details the data analysis results to date. A draft of this report shall be due 10 months after the start of the Option Year. The EPA will review and provide comment on this report within 21 days. The contractor shall incorporate any EPA comments and provide a final version of this report no more than 30 days after the receipt of the EPA's comments.

In Option Year Two, the Contractor shall perform the following Tasks:

1. Incorporate any EPA comments to the draft of Manuscript 3, clear the article through the EPA Clearance Process and submit the article to the specified Journal.
2. Incorporate journal reviewer comments and submit the final Manuscript 3 article to the journal for publication. The Contractor shall be responsible for all publication charges. The Contractor shall submit the final journal acceptance notice upon receipt.
3. Write a rough draft of the article, Manuscript 4, based on the reviewed outline suitable for EPA and any other coauthor's review. The EPA will provide comments on the draft within 21 days of receipt.
4. Incorporate any EPA comments to the draft of Manuscript 4, clear the article through the EPA Clearance Process and submit the article to the specified Journal.
5. Incorporate journal reviewer comments and submit the final Manuscript 4 article to the journal for publication. The Contractor shall be responsible for all publication charges. The Contractor shall submit the final journal acceptance notice upon receipt.
6. Write project descriptions; study protocols; analytical and statistical method sections; study population demographics descriptions; and all other study results sections in a

style suitable for an EPA Report. The EPA anticipates that it will prepare a summary document which describes the studies in Marietta, Mount Vernon and East Liverpool, Ohio with comparisons of manganese exposure and related health effects between the three communities.

7. Prepare a Final Report of no more than 5 pages which details the data analysis results to date. The Contractor shall include all of the data from the East Liverpool, Ohio study; any data from other sources used in comparisons between communities; the results of data analyses; any statistical programming code; all data documentation and / or metadata as an addendum to this Report. A draft of this report shall be due 10 months after the start of the Option Year. The EPA will review and provide comment on this report within 21 days. The contractor shall incorporate any EPA comments and provide a final version of this report no more than 30 days after the receipt of the EPA's comments.

D. Government Responsibilities

The government researchers will be responsible for annual renewals of the approval for the study from the EPA IRB of record, the University of North Carolina Institutional Review Board, and EPA Human Subjects Approval. The government researchers will obtain clearance and approvals for the public meeting presentation package with 14 days of receipt. The government researchers will provide comments on the outlines and manuscript drafts within 21 days of receipt. The government researchers will provide comments on the draft Final Reports within 21 days of receipt.